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| BOSE MCKINNEY & EVANS LLP | | | RINES, ROBERT D | |
| JAMES COLES | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|-----------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/520,419 | MEEK ET AL. |
| | Examiner Robert D. Rines | Art Unit 3626 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 1/26/07.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-4, 8-10, 22, 28, 29 and 32-43 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-4, 8-10, 22, 28, 29, and 32-43 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau.(PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 26 July 2007. Claims 30 and 31 have been cancelled. Claims 1, 3, 9-10, 22, 29, 32, 38, 39, and 43 have been amended. Claims 1-4, 8-10, 22, 28, 29, and 32-43 are pending.

Rejections of claims 1-4, 8-10, 22, 28, 29, and 32-43 are maintained as set forth in the previous Office Action mailed 31 January 2007, herein incorporated by reference. Applicant's amendments to claims 1, 3, 9-10, 22, 29, 32, 38, 39, and 43 are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

[2] Claims 1-3, 7-10, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) in view of Mebane (5,486,999).

(A) As per (currently amended) claim 1, Wong discloses a method of identifying patients at high risk of adverse health outcomes (col. 1 lines 9-12, col. 2 lines 31-45, col. 3 lines 42-48, col. 5 lines 13-25 and 31-40, and col. 15 lines 58-67) comprising:

(a) receiving (reads on “collecting”), storing, and extracting information from a patient record (reads on “individual”) for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, and col. 17 line 49 to col. 18 line 4);

(b) assigning, based upon information from a patient record, a separate value to each predictor of the set of predetermined criteria or predictors (Abstract lines 1-24, col. 2 lines 61-62,

col. 4 lines 62-66, col. 5 lines 3-12, col. 6 lines 44-51 and lines 64-67, col. 8 lines 18-22, col. 12 lines 27-39, and col. 13 lines 1-41);

(c) generating, based upon a prediction model and the separate values assigned to the predetermined set of criteria or predictors, risk subgroups (reads on “risk level”) of the patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (Fig. 6A-6B, Abstract lines 1-24, col. 1 lines 48-60, col. 2 lines 38-45 and lines 64-67, col. 3 lines 1-7, col. 3 lines 42-48, col. 4 line 65 to col. 5 line 3, col. 5 lines 13-25, col. 6 lines 44-63, col. 8 lines 33-35, col. 12 lines 7-18, col. 13 lines 51-60, and col. 18 lines 15-23 and lines 28-41);

(d) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(e) assigning, based upon information, a first dichotomous value, such as “1”, to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(f) assigning, based upon information, a second dichotomous value, such as “0”, to the separate value for the first predictor in response to defining that the first predictor is not an

indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

Wong fails to expressly disclose collecting self-reported information from an individual about their perceived health.

Mebane discloses collecting information from an individual in a questionnaire about their perceived health (col. 15 line 6 to col. 16 line 27, Appendix A – see col. 15-18).

Applicant has amended claim 1 directing the claimed "generating" or "determining" a risk level to "...a risk level of said individual becoming a member of the highest utilizing group using healthcare services at a predetermined level for any reason within a prospective time span;".

As per this element, Wong et al. disclose the use of patient healthcare events as derived from event records and claims records to generate an analysis file which in turn is employed to determine high risk subgroups (Wong et al.; col. 4, lines 51-67 and col. 5, lines 1-25). With regard to the utility of the subgroups, Wong et al. specifically disclose the "the resulting subset are those variables which best reflect a correlation to adverse health outcomes, consequently, resulting in substantial use of healthcare resources (e.g., funds)" (Wong et al.; col. 5, lines 18-25). Lastly, Wong et al. discloses additional stratification of "subgroups" of the basis of the predictive model by division of the groups in "5% or 10% increments of patient likely to have the adverse health outcome" (Wong et al.; col. 15, lines 40-57). Examiner submits that

assessment of patient health and claims history and ultimate stratification of subgroups of patients based on their individual potential for an adverse outcome reflective of "substantial use of healthcare resources", inherently produces a subgroup consisting of the "highest risk" individuals. Accordingly, Examiner maintains that the applied teachings of Wong et al., constitute determining "...a risk level of said individual becoming a member of the highest utilizing group using healthcare services at a predetermined level for any reason within a prospective time span;", at least insofar as presently claimed by Applicant.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Mebane within the method of Wong with the motivation of efficiently allocating medical resources based on the patient's needs (Mebane; col. 1 lines 45-59).

(B) As per claim 2, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong fails to expressly disclose presenting an individual with a self assessment questionnaire designed to elicit information from an individual for a predetermined set of predictive factors. However, Wong includes receiving (reads on "collecting"), storing, and extracting information from a patient data record or file (reads on "individual") for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line

4). Note, Wong receiving information in a patient file is considered to be a form of eliciting information from an individual.

Mebane discloses presenting a patient with a Lifestyle Questionnaire designed to determine selected lifestyle characteristics of the patient, wherein the questionnaire contains a set of input variables used to determine health care utilization (Fig. 4A, col. 2 lines 10-28, col. 5 lines 1-67, col. 6 Table 1, and col. 16 –18 Appendix A).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Mebane within the method taught by Wong with the motivation of improving the quality of treatment and outcomes for patients and reducing the cost for health care services by analyzing information about a patient's medical history and record (Wong; col. 2 lines 38-45).

(C) As per (currently amended) claim 3, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses a predetermined set of criteria or predictors, wherein the predictors include past healthcare use factors, such as number of hospitalizations, emergency services, or physician office visits, demographic factors, such as gender or age, and disease factors, such as diabetes or congestive heart failure (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-52, col. 5 lines 1-12, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-67, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

Examiner submits that data indicated when assessing predictive factors encompassing patient demographics, such as gender or age, and past healthcare use factors, such as hospitalizations, emergency services, or office visits as described by Wong, would provide informative content to one or ordinary skill in the art, regarding the patients "perceived health factors, disease factors, healthcare compliance factors, healthcare belief factors and healthcare preference factors". Accordingly, Examiner submits that the teachings disclosed by Wong with regard to contributing healthcare use factors encompasses Applicant's recitation of perceived, belief, disease, compliance, and preference factors.

The remainder of claim 3 repeats the same limitations as claim 2, and is therefore rejected for the same reasons given for claim 2, and incorporated herein. The motivation for combining Mebane with Wong is given above in claim 2, and incorporated herein.

(D) Claims 5-7 has been cancelled.

(E) As per claim 8, Wong discloses defining, based upon risk subgroups (reads on "risk level"), whether a high risk exists of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-25, col. 5 lines 31-40, col. 6 lines 44-51, and col. 13 lines 51-60), and defining, based upon information from a patient, a targeted intervention for a patient in response to defining that a high risk exists of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-

48, col. 5 lines 1-25, col. 5 lines 31-65, col. 6 lines 44-51, col. 13 lines 51-60, and col. 15 lines 58-67). Wong discloses "probability value exceeding a predetermined threshold" (see col. 14 line 49 to col. 15 line 13, col. 15 lines 40-54).

(F) As per (currently amended) claim 9, Wong discloses generating, based upon separate values assigned to each predictor and a model generated using multiple logistic regression, a risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 lines 49-58).

Applicant has amended claim 9 to reflect the determination of a risk of "becoming a member of the highest utilizing group using healthcare services..." presented in currently amended claim 1. This amended limitation is rejected under the Wong et al. disclosure as indicated above with respect to claim 1.

(G) As per (currently amended) claim 10, Wong discloses generating, based upon separate values assigned to the set of predictors and a model generated using multiple logistic regression, a probability or likelihood indicating the risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30, col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 line 60 to col. 15 line 67).

Applicant has amended claim 10 to reflect the determination of a risk of "becoming a member of the highest utilizing group using healthcare services..." presented in currently amended claim 1.

This amended limitation is rejected under the Wong et al. disclosure as indicated above with respect to claim 1.

(H) As per (currently amended) claim 22, Wong discloses:

(a) determining a resulting subset of variables from a set of variables or predictors best reflecting a correlation to patients who are at high risk for adverse health outcomes, consequently, resulting in substantial use of health care resources (e.g., funds) (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 38-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 4 line 61 to col. 5 line 25, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, col. 8 line 65 to col. 9 line 5, and col. 17 line 49 to col. 18 line 4); and

(b) defining points A, B, and C, wherein A represents the farthest past event, wherein B represents the present, wherein C can be defined by the last day for which an individual is still enrolled and eligible for benefits within a health plan, wherein A<B<C, and wherein the prediction of congestive heart failure hospitalization includes defining a time period between B and C such as 6 months used to predict CHF hospitalization within the next 6 months (col. 13 line 48 to col. 14 line 48). It is noted that the prediction time period of 6 months as discussed above in Wong is a "prospective time span."

Applicant has amended claim 22 to reflect the determination of a risk of "becoming a member of the highest utilizing group using healthcare services..." presented in currently amended claim 1. This amended limitation is rejected under the Wong et al. disclosure as indicated above with respect to claim 1.

The remainder of claim 22 repeats the same limitations as claim 1, and are therefore rejected for the same reasons given for those claims, and incorporated herein.

1. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) and Mebane (5,486,999) as applied to claim 1 above, and further in view of Silver (6,269,339).

(A) As per claim 4, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses receiving (reads on "collecting"), storing, and extracting information from a patient data record or file (reads on "individual") for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

Wong fails to expressly disclose presenting, to a web browser, a questionnaire that elicits information from an individual for a predetermined set of predictive factors, and receiving the information via a web browser in response to presenting the questionnaire.

Silver discloses presenting on a client computer system, over the Internet an interface for data input (reads on “web browser”), wherein the interface includes a questionnaire for inputting information from a patient for a set of relative risk factors (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), and receiving the information at a server over the Internet in response to presenting the questionnaire through an interface for data input (reads on “web browser”) (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), wherein the client computer system and the server communicate using the NetBIOS protocol (col. 7-8).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Silver within the method taught by Wong with the motivation of improving the quality of treatment and outcomes for patients and reducing the cost for health care services by analyzing information about a patient’s medical history and record (Wong; col. 2 lines 38-45), and providing a convenient means and decreasing the time to submit, update, and access information (Silver; col. 3 lines 49-51, col. 4 lines 48-64, and col. 8 lines 15-40).

2. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) and Mebane (5,486,999) as applied to claim 1 above, and further in view of Lash (US 2001/0020229 A1).

(A) As per (currently amended) claim 28, Wong and Mebane do not expressly disclose:
comparing said probability value to said predetermined threshold;

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identifying said individual as a high-risk person if said probability value

exceeds said predetermined threshold; and

identifying said individual as a low-risk person if said probability value does

not exceed said predetermined threshold.

Lash discloses this feature. Note Lash teaches:

comparing said probability value to said predetermined threshold (par. 8-12, 25, 38-39, 41-42, 49-50, claims 1-2);

identifying said individual as a high-risk person if said probability value exceeds said predetermined threshold (par. 8-12, 25, 38-39, 41-42, 49-50, claims 1-2); and

identifying said individual as a low-risk person if said probability value does not exceed said predetermined threshold(par. 8-12, 25, 38-39, 41-42, 49-50, claims 1-2).

Applicant has amended claim 28 to reflect the determination of a risk of "becoming a member of the highest utilizing group using healthcare services..." presented in currently amended claim 1.

This amended limitation is rejected under the Wong et al. disclosure as indicated above with respect to claim 1.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Lash within the method of Wong and Mebane with the motivation of targeting patients for preventative care based on a threshold (par. 5 of Lash).

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3. Claims 29, 34-36, 37-38, 39, 41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082) in view of Mebane (5,486,999) and Lash (US 2001/0020229 A1).

(A) As per (currently amended) claim 29, Wong discloses a method of identifying patients at high risk of adverse health outcomes (col. 1 lines 9-12, col. 2 lines 31-45, col. 3 lines 42-48, col. 5 lines 13-25 and 31-40, and col. 15 lines 58-67) comprising:

(a) receiving (reads on “collecting”), storing, and extracting information from a patient record (reads on “individual”) for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 44-51, col. 7 lines 12-21, and col. 17 line 49 to col. 18 line 4);

(b) assigning, based upon information from a patient record, a separate value to each predictor of the set of predetermined criteria or predictors (Abstract lines 1-24, col. 2 lines 61-62, col. 4 lines 62-66, col. 5 lines 3-12, col. 6 lines 44-51 and lines 64-67, col. 8 lines 18-22, col. 12 lines 27-39, and col. 13 lines 1-41);

(c) generating, based upon a prediction model and the separate values assigned to the predetermined set of criteria or predictors, risk subgroups (reads on “risk level”) of the patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (Fig. 6A-6B, Abstract lines 1-24, col. 1 lines 48-60, col. 2 lines 38-45 and lines 64-67, col. 3 lines 1-7, col. 3 lines 42-48, col. 4 line 65 to col. 5 line 3, col. 5 lines 13-25, col. 6 lines 44-63, col. 8 lines 33-35, col. 12 lines 7-18, col. 13 lines 51-60, and col. 18 lines 15-23 and lines 28-41);

(d) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(e) assigning, based upon information, a first dichotomous value, such as “1”, to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54);

(f) assigning, based upon information, a second dichotomous value, such as “0”, to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(g) generating, based upon separate values assigned to the set of predictors and a model generated using multiple logistic regression, a probability or likelihood indicating the risk level of the patient using healthcare resources at a predetermined level, such as cost, over a predetermined time interval or window (Abstract lines 1-24, col. 3 lines 42-48, col. 5 lines 1-30,

col. 5 lines 29-65, col. 6 lines 44-51, col. 12 lines 11-18, col. 13 lines 51-60, and col. 14 line 60 to col. 15 line 67).

Wong fails to expressly disclose collecting self-reported information from an individual about their perceived health.

Mebane discloses collecting information from an individual in a questionnaire about their perceived health (col. 15 line 6 to col. 16 line 27, Appendix A – see col. 15-18).

Applicant has amended claim 29 to reflect the determination of a risk of "becoming a member of the highest utilizing group using healthcare services..." presented in currently amended claim 1. This amended limitation is rejected under the Wong et al. disclosure as indicated above with respect to claim 1.

Applicant has further amended claim 29 to include limitations derived from cancelled claims 30 and 31. As per these elements, Wong fails to expressly disclose presenting an individual with a self assessment questionnaire designed to elicit information from an individual for a predetermined set of predictive factors. However, Wong includes receiving (reads on "collecting"), storing, and extracting information from a patient data record or file (reads on "individual") for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4). Note, Wong receiving information in a patient file is considered to be a form of eliciting information from an individual. Wong further discloses associating each said

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distinct predictor variable of said predetermined set of predictor variables to at least one of said plurality of questions (Abstract lines 1-24, col. 2 lines 61-62, col. 4 lines 62-66, col. 5 lines 3-12, col. 6 lines 44-51 and lines 64-67, col. 8 lines 18-22, col. 12 lines 27-39, and col. 13 lines 1-41).

As per the discussion of a questionnaire, note the discussion in claim 1 with regards to the Mebane reference. Mebane discloses presenting a patient with a Lifestyle Questionnaire designed to determine selected lifestyle characteristics of the patient, wherein the questionnaire contains a set of input variables used to determine health care utilization (Fig. 4A, col. 2 lines 10-28, col. 5 lines 1-67, col. 6 Table 1, and col. 16 –18 Appendix A). Mebane further discloses assigning said second dichotomous value to any distinct predictor variable of said predetermined set of predictor variables for which said at least one of said plurality of questions associated with said any distinct predictor variable is unanswered or answered inappropriately (col. 14 line 24 to col. 15 line 26: see the discussion of a patient having a low score but having a narcotic dependency. These patients are identified as high risk even though they have a low score. Examiner maintains that this is a form of answering incorrectly or leaving a question unanswered.)

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Mebane within the method taught by Wong with the motivation of improving the quality of treatment and outcomes for patients and reducing the cost for health care services by analyzing information about a patient's medical history and record (Wong; col. 2 lines 38-45).

Wong and Mebane do not expressly disclose:

comparing said probability value to said predetermined threshold;
identifying said individual as a high-risk person if said probability value exceeds said predetermined threshold; and
identifying said individual as a low-risk person if said probability value does not exceed said predetermined threshold.

Lash discloses this feature. Note Lash teaches:

comparing said probability value to said predetermined threshold (par. 8-12, 25, 38-39, 41-42, 49-50, claims 1-2);
identifying said individual as a high-risk person if said probability value exceeds said predetermined threshold (par. 8-12, 25, 38-39, 41-42, 49-50, claims 1-2); and
identifying said individual as a low-risk person if said probability value does not exceed said predetermined threshold(par. 8-12, 25, 38-39, 41-42, 49-50, claims 1-2).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Lash within the method of Wong and Mebane with the motivation of targeting patients for preventative care based on a threshold (par. 5 of Lash).

(C) Claims 30 and 31 have been cancelled.

(D) As per claims 34-35, Wong, Mebane, and Lash do not expressly disclose using a scannable form or IVR telephone system to elicit responses. However, the Examiner respectfully submits

that it is well known in the surveying arts to use both scannable forms and IVR telephone systems to survey patients. The motivation for modifying the prior art of Wong, Mebane, and Lash being to ensure that multiple methods of inputting answers are used to accommodate many patients.

(E) As per claim 36, Wong discloses the following for a single predictor:

(a) defining, based upon information, whether a first predictor is reflective of a correlation to a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 14 lines 59-67, and col. 15 lines 1-54);

(b) assigning, based upon information, a first dichotomous value, such as “1”, to the separate value for the first predictor in response to defining that the first predictor is an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60, col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54); and

(c) assigning, based upon information, a second dichotomous value, such as “0”, to the separate value for the first predictor in response to defining that the first predictor is not an indicator of a high risk of a patient using health care resources at a predetermined level, such as cost, over a predetermined time interval or window (col. 2 lines 62-67, col. 3 lines 1-7 and 57-60,

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col. 4 lines 24-44, col. 4 lines 51-60, col. 5 lines 1-25, col. 6 lines 44-51, col. 7 lines 22-64, col. 9 lines 1-5, col. 12 lines 7-10, col. 13 lines 22-41, col. 14 lines 59-67, and col. 15 lines 1-54).

(F) As per claim 37, Wong discloses wherein said predetermined predictive model is a logistic regression predictive model (col. 14 line 59 to col. 15 line 13).

(G) As per (currently amended) claim 38, Wong discloses the equation in claim 37. See col. 14 line 59 to col. 15 line 13. Lash discloses this equation also (par. 28-30).

Applicant has amended claims 38, 39, and 43 to reflect the determination of a risk of "becoming a member of the highest utilizing group using healthcare services..." presented in currently amended claim 1. This amended limitation is rejected under the Wong et al. disclosure as indicated above with respect to claim 1.

(H) Claims 39, 41, and 43 repeat the limitations of claims 29-31, 34-36, and 37-38, and are rejected for the same reasons as those claims.

4. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082), Mebane (5,486,999), and Lash (US 2001/0020229 A1) as applied to claim 29 above, and further in view of Joao (5,961,332).

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(A) As per (currently amended) claim 32, Wong, Mebane, and Lash fail to expressly disclose identifying said individual as a high-risk person if said individual fails to answer more than a predetermined number of said plurality of questions of self assessment questionnaire. Joao discloses this feature. See col. 35 line 46 to col. 36 line 35. At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the features of Joao within the method taught collectively by Wong, Mebane, and Lash with the motivation of ensuring that patients enter valid data and that valid data is analyzed (Joao; col. 2 lines 31-40).

Applicant has amended claim 32 to depend from claim 29 as opposed to now cancelled claim 30.

5. Claims 33 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. (5,976,082), Mebane (5,486,999), and Lash (US 2001/0020229 A1) as applied to claim 29 and 39 above, and further in view of Silver (6,269,339).

(A) As per claim 33 and 40, the relevant teachings of Wong are as discussed in the rejections above, and incorporated herein.

Wong discloses receiving (reads on “collecting”), storing, and extracting information from a patient data record or file (reads on “individual”) for a predetermined set of criteria or predictors (Fig. 1A-1B and 4, Abstract lines 1-24, col. 2 lines 49-61, col. 3 lines 58-67, col. 4 lines 24-34, col. 5 line 66 to col. 6 line 16, col. 6 lines 26-51, col. 7 lines 12-21, col. 8 lines 45-60, col. 12 line 46 to col. 13 line 17, and col. 17 line 49 to col. 18 line 4).

Wong, Mebane, and Lash fail to expressly disclose presenting, to a web browser, a questionnaire that elicits information from an individual for a predetermined set of predictive factors, and receiving the information via a web browser in response to presenting the questionnaire.

Silver discloses presenting on a client computer system, over the Internet an interface for data input (reads on “web browser”), wherein the interface includes a questionnaire for inputting information from a patient for a set of relative risk factors (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), and receiving the information at a server over the Internet in response to presenting the questionnaire through an interface for data input (reads on “web browser”) (Fig. 3-6, col. 3 lines 25-48, col. 7 line 59 to col. 8 line 40, and col. 9 line 42 to col. 10 line 26), wherein the client computer system and the server communicate using the NetBIOS protocol (col. 7-8).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Silver within the method taught by Wong with the motivation of improving the quality of treatment and outcomes for patients and reducing the cost for health care services by analyzing information about a patient’s medical history and record (Wong; col. 2 lines 38-45), and providing a convenient means and decreasing the time to submit, update, and access information (Silver; col. 3 lines 49-51, col. 4 lines 48-64, and col. 8 lines 15-40).

Response to Remarks

Applicant's remarks filed 26 January 2006 have been fully considered but they are not persuasive. The remarks will be addressed below in the order in which they appear in the response filed 26 January 2006.

Applicant remarks that the combination of Wong et al. and Mebane, does not describe the process defined by claim 1 of present application.

Specifically, Applicant remarks:

"Wong only discusses use of healthcare resources with regard to congestive heart failure (CHF). Wong does not address the numerous other reasons a person would utilize healthcare resources or become a member of the highest utilizing group using healthcare services for any reason."

In response, Examiner agrees that Wong is directed to assessment of individual patients and patient subgroups for risk and associated healthcare costs associated with congestive heart failure (CHF). However, as noted with regard to currently amended claim 1, the functional method steps disclosed by Wong et al. with respect to CHF are analogous to Applicant's claimed steps directed to prediction of healthcare use "for any reason". Examiner maintains that it would have been obvious to one of ordinary skill, as a matter of user choice/design choice, to input variables and

data related to other diseases in the manner described by Wong to achieve the same predictive result with respect to another disease (i.e., "for any reason").

Applicant further remarks:

"Mebane does not determine individuals that could become members of the highest cost group using healthcare services for any reason regardless of the appropriateness of the utilization."

In response, Examiner agrees with Applicant's supportive statement to the effect of "the Mebane invention involves performing an analysis based on several factors relating to a patient's lifestyle and health care utilization to identify inappropriate health care utilization". Examiner further agrees with Applicant's notation that Mebane is directed to determining inappropriate over utilization of healthcare services. However, Examiner applies Mebane merely to evidence that the use of a self-reporting questionnaire is well known in the art as a means of aggregating patient data for use in making assessments of an individual's potential for utilization of healthcare resources. Examiner maintains, as set forth above, that applied teachings of Wong et al. address Applicant's recited limitations directed to generating an assessment of healthcare utilization "...for any reason".

Applicant remarks that the combination of Wong et al., Mebane, and Lash does not describe the process defined by claim 29 of present application.

Applicant remarks:

Mebane fails to teach or disclose "...assigning said first dichotomous value to any distinct predictor variable of said predetermined set of predictor variables for which said at least one of said plurality of questions associated with said any distinct predictor variable is unanswered or answered inappropriately"

In support of the above noted remark, Applicant states:

"Mebane col. 14 line 24 to col. 15, line 26 explicitly states "A score of '1' is assigned to each affirmative response and a score of '0' is assigned to each negative response". However, nowhere in this section is any discussion of "questions...unanswered or answered inappropriately" as recited in amended claim 29."

Applicant further notes "The cited section of Mebane does discuss threshold of identifying a patient as a high risk patient if X out of Y questions are answered a particular way" (Mebane col. 14, lines 40-42, col. 14, lines 46-49 and col. 14, lines 55-59).

Examiner agrees with Applicant that Mebane fails to address specific "what if" scenarios involving "unanswered" questions or "inappropriately" answered questions. However, Examiner submits that a scenario in which a question is unanswered or answered "inappropriately" is accommodated by Mebane's statement, as noted by Applicant, to the effect that identification of

a high risk patient is based on the patient's responses as answered "in a particular way". Examiner further submits that it would be obvious to one of ordinary skill in the art that "unanswered" or "inappropriately" answered questions would be categorized as either "negative" or "affirmative", and assigned a '1' or a '0', depending on whether an unanswered question or inappropriate answer is viewed as a "negative" or an "affirmative" response by the designer of the specific questionnaire (i.e., content design/user choice).

Regarding Applicant's recitation of limitations directed to specific scoring scenarios involving the handling/scoring of unanswered questions and questions answered inappropriately as presented in claims 39 and 32, Examiner maintains, as presented above, that the specific scenarios and categorization of potential patient responses is a matter of design choice with respect to the design of specific questions.

Applicant remarks:

"In the rejection of claims 34 and 35, the Examiner "submits that it is well known in the surveying arts to use both scannable forms and IVR telephone systems to survey patients."....Applicant's respectfully request that the Examiner provide documentary evidence of such knowledge at the time of the invention..."

In response, Examiner maintains that the use of scannable forms and IVR telephone system to survey patients was well known in the art at the time the invention was made as evidenced by

Brill (scannable forms) (United States Patent #5,435,324) (Brill; col. 4, lines 52-67) and Iliff (IVR surveys) (United States Patent #6,234,964) (Iliff; col. 6, lines 1-17 and col. 9, lines 12-49).

In conclusion, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 26 July 2007 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Wong et al., Mebane, Lash, Silver, and Joao, based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (31 January 2007), and incorporated herein.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert D. Rines whose telephone number is 571-272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

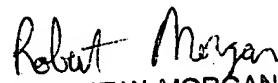
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RDR



12/21/07



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